UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: BOSTON SCIENTIFIC CORP., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION — MDL NO. 2326

THIS DOCUMENT RELATES TO

HANNA WILKERSON,

Plaintiffs,

vs.

BOSTON SCIENTIFIC CORPORATION,

Case No. 2:13-cv-4505

Defendant.

Videotaped Deposition of Kelly A. Booth, M.D.
Thursday, November 13, 2014
Huntersville, North Carolina
At 12:35 p.m.

Reported By: LeShaunda D. Cass-Byrd, CSR, RPR

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EXHIBIT
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the day or where the Depends pads or something like that for incontinence or severity of bulge and pressure discomfort, there is a different level of tolerance, depending on the individual patient. So how to parse out whether the patient is leaning towards a surgical plan versus a medical plan, is has a lot to do with what the individual desires.

Q. And if -- if a patient appears to be a surgical candidate, what are some of the options that you would offer to her?

A. Well, the standard of care is -- for urinary incontinence is a tension-free vaginal tape. In patients that have no symptoms, and you find on exam -- you just so happen to find the laxity of the bladder, the posterior compartment, or at the apex some decent. And they are not having symptoms, you don't -- you don't -- you may say, "Oh, you might -- your bladder is falling just a little bit." But you don't move towards offering them any kind of surgical management if they are not systematic.

But from the standpoint of urinary incontinence, the gold standard is -- now, it can just be vaginal tape. And I came along in the days of using a Burch procedure retropubic sling. Did Burch procedures laparoscopically and open -- for the most

part, open -- at Duke.

And when I came here, continued to do them until it was an accepted and gold standard literature-proven way to decrease complications and improve outcomes, long term, by using the tension-free tape.

Now, for years, the urologists had been doing slings and whatnot. But they were not doing them tension free, and so the outcomes for retention and all were very high. So it was something that we kind of watched and waited until good data came out.

And as it became accepted gold standard, then the tension-free tape surpassed the -- the Burch procedure as the recommended standard of care by our college, ACOG. So...

Q. And is that still true today?

A. Yes.

Q. When you use the term "tension-free vaginal tape," is that a generic term that encompasses different brands?

A. Yes.

Q. And would the Advantage Fit fall within that description?

A. Yes.

Q. Let me go back a little bit to your

but -- but do not have urinary incontinence from detachment of the urethra or a drainpipe or ISD urethra, intrinsic sphincteric deficiency.

So urodynamics do a wonderful job of teasing that out, to be certain that we are not providing a surgical option for somebody that would be better served with a medical option.

Q. Okay. And we will talk about the urodynamics in a minute. But finishing out this record, you wrote, She needs anterior compartment repair. What do you mean by that?

A. An anterior repair. Basically, anterior colporrhaphy, which is to plicate the fascial tissue. Almost like the repair of a hernia on the abdominal wall, to basically bring the strong tissue together and reduce the hernia back where it belongs.

Q. And it looks like you discussed with her that -- the repair that you thought that she would likely need and the tension-free vaginal tape, but you wanted her to go to get the urodynamics first; is that correct?

A. Right.

Q. You noted that you spent 45 minutes face-to-face time with the patient, greater than 40 percent of that in counselling and coordination of

care. Does that mean that you spent greater than 50 percent of that time actually talking with Ms. Wilkerson?

A. Yes.

Q. And in the conversation that you had with her, did you explain the interior repair and the use of the tension-free vaginal tape?

A. We talked about that. And we talked about why I thought the -- usually would discuss why I thought that the leakage got better with time, just to sort of explain the physiology of why she noticed the bulge get worse but the leakage got better. Because that is confusing to patients.

And then they say, "Well, why do you want to fix the incontinence if I'm not having an incontinence problem?"

So -- and I -- you know, I think I probably introduced that idea of a TVT, but wanted to go into greater detail with her about that at a later time. We -- since it's been a while and I don't have every detail of what was discussed -- but I imagine that is what I did.

Q. That would have been consistent with your usual practice?

A. Absolutely.

integrity.

So we eliminate the suspicion for intrinsic sphincteric deficiency if the integrity of the urethra is good. But with the finding of the leak with Valsalva at 300 cc's, that is consistent with genuine urinary stress incontinence -- or stress urinary incontinence, but without a intrinsic sphincteric deficiency component. So that basically indicates that the leakage was just caused by detachment of the urethra from the fascia.

So to -- to assist with that, once -- reducing that hernia, repairing that cystocele with an anterior repair, if we left it at that, we would end up with leakage. So doing that would be doing her dis- -- a disservice. And I think then we -- when I got these results, we discussed what would need to be done to -- to assist with that.

Q. So is it fair to say that the urodynamics confirm what you suspected on your exam --

A. Uh-huh (affirmative).

Q. -- you expected to find this?

A. Yes.

Q. And confirmed your -- your preliminary plan to do the anterior repair and use the TVT to support her urethra?

A. Yes.

Q. Okay. And then she came back to see you on February 12th, 2010?

A. Yes.

Q. And --

A. To discuss the urodynamics.

Q. -- and it looks like you spent the entire visit in discussion with her rather than performing any exams; is that correct?

A. Right.

Q. Because you wanted to spend some time doing a detailed discussion of the surgical management that were you proposing?

A. Right.

Q. And did you explain to her what you've just explained to us about why she was not having leakage but still needed a repair to the -- to the urethra --

A. Yes.

Q. -- or support?

A. Yes. Yes.

Q. Do you remember Mrs. Wilkerson specifically or --

A. Uh-huh (affirmative).

Q. -- are you relying on your records?

You remember her?

A. Yeah, I do.

Q. And under your plan you recorded that you were going to proceed with the anterior repair and the TVT and cystopathy. We haven't talked about cystopathy. What does that mean?

A. Cystopathy is performed after any anterior repair and/or tension-free tape, in my practice. And really, probably likely, the majority of GYNs, to confirm that there is no injury to the urethra or the ureters or the bladder itself. Because you are operating basically in close proximity to all of the structures of the bladder.

And cystopathy is performed at the completion of both procedures to confirm that there is no harm to those organs -- or that organ and the ureters.

It is performed by taking a lighted scope into the bladder and instilling normal saline into the bladder -- or sterile water -- to look around and make sure that there is no evidence of the sutures that you have used to repair the prolapse or the tension-free tape that you have used to secure the urethra into its normal and natural angle.

And the way that the tension-free tape that I typically use, the way that that is easy to discern

is by looking laterally with a 70 degree cystoscope to see if there is any evidence of the introducer.

So when the procedure is performed, the introducer is basically left -- left there before the cystopathy is complete, to confirm that there is no mal placement of the tape. And the tape itself is contained within this introducer, which is a bright blue color in the Advantage Fit device.

And if you look laterally on each side of the bladder, you will not see the -- the blue color and you will know that you are not -- you have not penetrated or perforated the bladder with the tape.

And then at that point, the introducer can be removed. So we -- you know, we -- we can fast-forward to the procedure. Or I will wait for your question.

Q. Okay. We will get there. I just want to finish going over what you discussed with her.

A. Uh-huh (affirmative).

Q. You documented that you reviewed with the patient the risks of bleeding, infection, damage to surrounding organs, including bladder, bowels and ureters. Is that something that you routinely do?

A. Yes.

Q. And did with Ms. Wilkerson?

A. Yes.

Q. And you also discussed with her -- with her the risk of a possible recurrence of her stress incontinence.

A. Yes.

Q. And recurrence of her prolapse.

A. Uh-huh (affirmative).

Q. And mesh erosion. What do you mean by that?

A. Mesh erosion is when the tape, the tension-free tapes that are on the market are basically seen as a foreign body by the -- by the vagina. And in some cases, they can be extruded through the vagina and cause irritation, discomfort with intercourse, vaginal discharge, some spotting or bleeding.

And if that is to happen, it is something that we talk about how it would be managed postoperatively, if that were to happen. And also talk about the fact that it -- that could happen remote from the time of -- of the procedure, and what to watch out for symptom-wise if it were to happen.

And so we discussed that in great detail. The -- I do discuss that the mesh, in the case of the TVT, is a very limited site in the vagina where there

is not a whole lot of area for the mesh to erode or protrude and cause a problem.

So that if -- if it were to happen, we discuss if -- that it might require another procedure, either in the office or in the hospital, to help either remove or just advance vagina over the mesh, because it can be irritating.

Now, mesh erosion into the bladder is not something that I have seen in the practice of using a TVT and placing it properly, if the -- if the cystopathy is negative.

So I suppose that erosion into the bladder is something that is reported in cases. But we discuss mesh erosion related to the vagina because that is the most common circumstance. And that -- as far as which way mesh would erode -- erode.

So anybody that is going to have placement of a foreign body, a tension-free tape or sacrocolpopexy, will be counseled on vaginal mesh -- mesh erosions and what the symptoms are of that so they can watch out for it.

Q. So that is something you went over with Ms. Wilkerson?

A. Yes.

Q. And in the cases that you have you seen of

mesh erosion, has that been something that you can sometimes simply treat on outpatient basis?

A. Yes. Many of the cases respond well to just vaginal estrogen cream, which causes advancement of healthy mucosa.

Q. And you also discussed with her the possible risk of urinary retention as well?

A. Yes.

Q. And then you documented that knowing these risks, the patient was willing to proceed and that you answered her questions?

A. Yes.

Q. Okay. And that you spent 30 minutes face-to-face time with her, was greater than 50 percent of the time in counseling and coordinating?

A. Yes.

Q. So when you finished explaining these risks to Ms. Wilkerson, you had informed her that she could have a recurrence of both her prolapse and her stress urinary incontinence. You had explained that to her?

A. Yes. Yes.

Q. And -- and as far as you can tell, she understood that?

A. Oh, yes. Uh-huh (affirmative).

Q. And I don't think this is in your chart.

Let me just show you the consent form.

(Booth Exhibit 3 was marked for identification.)

BY MS. PACKER:

Q. Which comes from the hospital chart. And I apologize for the poor copy.

A. Oh, it looks pretty good to me. I have seen worse.

Q. So -- so -- so have we.

Is this a consent form that you or somebody operating under your supervision or working under your supervision had Ms. Wilkerson sign?

A. Yes.

Q. And who would have gone over this with her. Do you know?

A. Myself, and Susan Hales, who is our, at that time, posting folks for surgery.

Q. And so the signature at the bottom where it says physician is your signature?

A. Yes.

Q. Okay. So you went over with this in addition to Susan?

A. Yes.

Q. And if she had had any questions, you would have answered them?

A. Yes.
Q. And then you asked the patient to sign and initial on the bottom left; is that correct?
A. Yes.
Q. Okay. Let's go now to the next thing that happened, which I believe would have been the procedure itself.
A. Okay.
Q. Do you have that note?
A. I do.
Q. And it looks like the -- the date of the operation was March 9th, 2010.
A. That is correct.
Q. And so the consent form would have been signed in your office on a prior preop visit?
A. Right.
Q. Okay.
A. Which was February 12th, 2010.
Q. Okay. So referring to your operative note, can you walk us through the procedure that you performed?
A. Sure. The preoperative diagnosis is stress urinary incontinence and a cystocele. The procedures described are tension-free vaginal tape cystopathy and anterior colporrhaphy, also known as an anterior

Q. -- so where it says dilation, it should say violation.

A. Uh-huh (affirmative).

Q. Okay.

A. So then --

Q. Let me stop you before you get any further.

Under description of the procedure it says: Following detailed informed consent. Did you review the informed consent again before the surgery?

A. Yes. In the preoperative area, just to make sure there is no further questions, oftentimes with the significant other, if they were not able to be there at the signing of the consent form in the office. That's just a standard of care, and we do that with every single case -- or I do that with every single case. And it's actually required by the hospital as well.

Q. And would that discussion immediately prior to surgery include a review of the potential risks and complications, as you went over in your office before?

A. Yes. And answer any questions related to those risks.

Q. Okay. You can go ahead and just walk us through the procedure, if you would.

A. So following detailed informed consent, the

patient was taken in the operating room and placed in the dorsal lithotomy position. And after successful general anesthesia was achieved, the patient was placed in the Allen stirrups and sterilely prepped vaginally and perineally, and draped in the usual fashion.

In-and-out catheterization of the bladder was performed and the weighted speculum was inserted into the vagina.

The vaginal apex was grasped with Alex -- Allis clamps, and the cystocele was isolated and evaluated. Approximately 20 cc's or ml's of 1 percent lidocaine with one and 200 concentration of epinephrine was injected to the vaginal mucosa.

The vaginal mucosa was thin in size in the midline, and the mucosa was dissected off the underlying paravascular fascia using sharp dissection with the Stroli scissors.

The midline defect was identified and a series of interrupted imbricating sutures of 2-0 Vicryl were placed to plicate the perivascular fascia in the midline.

The vaginal mucosa was then trimmed and reapproximated, using 3-0 Vicryl in a running, walking fashion. Through a separate incision in the

mid-urethral area, the TVT mesh was introduced.

Once again, 1 percent lidocaine was injected into the vaginal mucosa, and half percent Marcaine injected to the space of Retzius at the sites were trocars were to be placed.

These sites were marked, two-fingerbreadths lateral to the midline, over the pubic symphysis.

The vaginal mucosa was undermined to the urogenital diaphragm. And using the Stroli scissors in the Boston Scientific -- it says Align Fit, but it's supposed to be Advantage Fit --

Q. Okay.

A. -- was assembled and placed through the urogenital diaphragm. The patient right -- it says fifth trocar -- but right trocar was then directed to the isolateral shoulder on the right side and exited through the appropriate demarcation at the level of pubic symphysis.

In a similar fashion, the trocar was introduced through the patient's left urogenital diaphragm. And directing towards the -- the trocar towards the demarcated site on the left pubic symphysis, directing towards the lateral shoulder on the left.

This trocar was introduced through the

demarcated site. One amp of indigo carmine had been introduced by anesthesia and cystopathy was performed to evaluate for any evidence of bladder injury. Both ureteral orifices were spilling indigo carmine-tinged urine vigorously.

The Mayo scissors were placed beneath the urethra as the mesh was drawn through the face of Retzius and trimmed in order to allow no tension to be placed on the mesh.

The vaginal mucosa was reapproximated over the mesh, using a horizontal imbricating suture of 40 VICRYL. Vaginal packing with Premarin cream was placed and a Foley catheter was placed to straight drain.

Of note, while the trocars were being directed on both right and left side, the bladder was deviated to the opposite side using the catheter guide sheets in a Foley. This maneuver was performed in order to protect the bladder from injury.

At the completion of the case, all sponge, needle, and instrument counts were correct times two and the patient was awakened, excavated and taken to a recovery room, alert and in stable condition.

Q. Did this operation proceed without any complications?

reputable resources to review before they decide to go through with a TVT.

Now I don't offer the mesh kit repair, along with the rest of my partners. So...

Q. With respect to the TVT repair, in your experience, what has been your complication rate?

A. Oh, extremely low. The only -- I have not had any bladder injuries or urethral injuries. The complaints of mesh erosion are numbering three or four. I'm trying to -- one was actually the same patient. So I would consider that four. But it's three patients. But the erosion -- an erosion occurred the second time on somebody that was very atrophic in the vagina.

And as far as discomfort or pain, recurrence of incontinence, it's been a -- a joy of a procedure to perform, from the standpoint of minimal complications and very -- so much better recovery than a Burch procedure. So it's been good, all-around outcomes.

Q. It's still a procedure that you perform on patients today?

A. Yes. Yes. And would advise a family member to receive or -- yeah, absolutely.

(Booth Exhibit 6 was marked for

identification.)

BY MS. PACKER:

Q. Okay. Let me show you what I have marked as Exhibit 6, which is the directions for use -- make sure I don't give you my highlighted copy -- the directions for the Advantage Fit. Is that a document that you reviewed at some point in the past?

A. Yes.

Q. I assume it's not something --

A. Prior to use.

Q. -- you review every time. But --

A. No.

Q. -- but when you first started using the product?

A. Yes.

Q. And let me ask you, if you would, to turn to the third page of the document. Actually, the fourth page, where it says, Adverse events.

A. Okay.

Q. Are -- and I will give you a second to read it. But are the adverse events that are listed here all potential adverse events or complications that you were aware of through your general knowledge as a physician?

A. Yes.

Q. So certainly you knew, from your own experience, that there were potential risks of a -- a pain or of failure of the procedure?

A. Yes.

Q. Okay. Thank you.

In making the decision about what of -- I'm moving away from that document now, Doctor.

A. Okay.

Q. In making a decision about whether you are going to use a medical device or not in your patients, we have already discussed CME training that you received, literature, confirming with your colleagues. Are there any other sources of information that you would typically rely on in making a decision that I am or am not going to use that particular medical device?

A. I can't think of anything other than that. I mean, conferences, like SGS, the Society for Gynecologic Surgeons, would be an additional -- you know, reputable conferences. And that is about all I can think of.

Q. There has been some testimony in -- in this mesh litigation, generally about materials safety data sheet for the raw material that was used to make some of the mesh. Is that a type of document that you are familiar with?

the FDA's inquiry, provided by a compatibility data, would that be reassuring to you as a physician?

A. Yes.

Q. Would you rely on the FDA to make the ultimate decision about approval of this device, having considered the material safety data sheet and Boston Scientific data as supplied to the FDA?

A. Yes, that I would trust the FDA --

Q. And --

A. -- for that information.

Q. And in your decision-making process as a physician, you would rely on the FDA and you would also rely on -- as you've used the term -- evidence-based literature?

A. Yes.

Q. And not on a -- one document that is a manufacturing-related document; is that fair to say?

A. Yes. I would be just a little skeptical. Not -- I mean, just because it's almost like one little disclaimer. And as I look at -- I don't know. I mean, I -- I would definitely rely more on a body of literature to tell me what outcomes were, then a -- a disclaimer to basically throw the baby out with the bath water, so to speak, just say, "Oh, well this has got to be all bad," in the situation. Because the

chemical foundation or makeup of this device is not to be used in the human body. So I -- I wouldn't look at this and say, "Oh, absolutely. I'm not putting any more TVTs in at all."

Q. And from your knowledge of the literature, is there a well-documented, long and safe use of polypropylene for the purpose of TVT mesh?

A. Yes.

Q. And I believe you now have with you a copy of your CV. Can we mark that?

A. Sure. It's a little bit ancient.

Q. That is okay. You don't have any reason to keep it current.

A. That is right. Not looking for a new job.

Yeah. This is fine. The only thing I say, the ACOG member. Oh, it's in here. That is okay. Good. And then strike the AMA. Sorry.

Q. That is okay. So you have gone -- gone ahead and made that change?

A. Yes.

(Booth Exhibit 8 was marked for identification.)

BY MS. PACKER:

Q. So Exhibit 8 is your CV --

A. Do you want one of these?